

## CLINICAL ETHICS

## Law and policy in the era of reproductive genetics

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The extent to which society utilises the law to enforce its moral judgments remains a dominant issue in this era of embryonic stem cell research, preimplantation genetic diagnosis, and human reproductive cloning. Balancing the potential health benefits and diverse moral values of society can be a tremendous challenge. In this context, governments often adopt legislative bans and prohibitions and rely on the inflexible and often inappropriate tool of criminal law. Legal prohibitions in the field of reproductive genetics are not likely to reflect adequately the depth and diversity of competing stakeholder positions. Rather, a comprehensive and readily responsive regulatory policy is required. Such a policy must attend to the evolving scientific developments and ethical considerations. We outline a proposal for effective, responsive, and coherent oversight of new reproductive genetic technologies.

In *The Enforcement of Morals* Lord Patrick Devlin asked: "To what extent should society use the law to enforce its moral judgments".<sup>1</sup> Fifty years later, in an era of stem cell research, preimplantation genetic diagnosis, and the prospect of human cloning, this has emerged as one of the dominant questions for those struggling to develop regulatory policy.

Most would agree with the claims that the law often reflects public morality, that what is ethical ought to be permitted, and what is unethical ought to be prohibited.<sup>2</sup> Few other areas of social activity highlight this challenge more than reproductive genetics where diverse moral values and proposed health benefits require such careful balancing. Finding this balance can be a tremendous challenge. In Canada, for example, the process of crafting legislation is still underway—ten years after legislative recommendations were detailed by the Royal Commission on New Reproductive Technologies.<sup>3</sup> Despite ongoing calls for greater regulation, however, the United States has produced few laws specifically designed to meet the challenges created by advances in reproductive genetics. In recent years, several other countries, including France, Sweden, the United Kingdom, Germany, Japan, and Brazil, and international organisations such as UNESCO, the World Health Organisation, and the Council of Europe have also attempted to craft legislative and policy solutions.

Too often, we believe, the search for a regulatory response to certain scientific developments has led governments to adopt simple bans and prohibitions. We recognise that this approach is often a result of political or jurisdictional constraints or the result of a lack of other regulatory options. Using the law in such a manner is, however, frequently an inappropriate means of regulating behaviour in this complex and dynamic area. With rare exception, legal prohibitions are blunt—that is, they tend to be either overly permissive or overly restrictive—inflexible, and incapable of reflecting the depth and diversity of ethical views inextricably linked to the policy debates surrounding reproductive genetics.

There seems little doubt that reproductive genetics will have profound and ongoing implications for both individuals and society. It is imperative that effective, responsive, and coherent oversight be adopted in order to bring thoughtful public policy to this field. In this paper, we highlight several

reasons why it is difficult to craft policy that is both comprehensive and responsive to the evolving science and bioethical considerations. We seek to emphasise the shortcomings of rigid prohibitory laws and describe another regulatory strategy that may be more effective.

## THE CHALLENGE OF REGULATING REPRODUCTIVE GENETICS

The challenges to responsible regulation of reproductive genetics are numerous. These include the complexity of the scientific information; the fact that policy making in this context will often engage strongly held moral values, and, the fact that numerous political dilemmas, such as the polarising effect of the abortion debate in the United States, often frustrate attempts to generate an in depth discussion of many of the most central issues. In this paper, we focus on four additional challenges: (1) the limited guidance of public opinion; (2) the inadequacy of health and safety arguments; (3) the difficulty of relying solely on intuitive ethics, and (4) the rapid pace of scientific and technological development in this field.

### The limits of public opinion

Important public opinion research has been done in the area of reproductive genetics and yet relying on such data presents certain problems.<sup>4–6</sup> Although surveys of public opinion consistently show strong opposition to human reproductive cloning and support for embryonic stem cell (ES cell) research,<sup>6–8</sup> it is unclear how "deep" these opinions go and whether the public accepts the potential inconsistency that follows from the positions they express. Support for ES cell research—for example, can be found at a certain level of generality, but breaks down depending on the sources of ES cells.<sup>9</sup> The data collected in a survey conducted by Canadian News Wire reveals strong support of the use of spare embryos for stem cell research regardless of religious and federal political preference.<sup>10†</sup>

In addition, while public attitudes about reproductive cloning seem relatively clear and settled—the public appears

† The data was collected by Environics between March 7 and 24 2002 and involved 2014 Canadians.

to be overwhelmingly opposed—public opinion about other techniques, such as the creation of embryos to obtain ES cells for research purposes, and therapeutic cloning, appears relatively divided and may continue to fluctuate. Among the reasons for this fluctuation may be the inability to come to agreement on the definitions of the terms themselves. The distinction between “therapeutic” and “reproductive” cloning—for example, may not be as relevant to those who believe that the former inevitably gives rise to the latter. Under such conditions it should not be surprising that consensus is difficult to find through polling public opinion.

For this reason, those responsible for making policy should not exclusively rely on “social consensus” as a rationale for the enacting a variety of prohibitive regulations. Nevertheless, though a government may have a variety of reasons for the development of regulatory policy, societal condemnation is often invoked as the primary justification for rigid bans,<sup>11</sup> even if social consensus is absent or unclear. In Canada, research has consistently shown that a majority of the public believes that use of therapeutic cloning technology is potentially acceptable.<sup>6 12 13 14</sup> Despite such data, which is consistent with data from other jurisdictions,<sup>6</sup> the Canadian government recently recommended a ban on therapeutic cloning based, in part, on the (obviously inaccurate) assessment that there is a “broad social consensus”.<sup>11 15</sup>

This strategy is hardly surprising. In most liberal democracies, appeal to widespread publicly held beliefs could be viewed as politically necessary where strong prohibitory laws are to be put into operation. Indeed, commentators have argued that criminal like prohibitions should be used with restraint and should generally be reserved for areas where there is a high degree of social consensus.<sup>16–18</sup> If strong prohibitions are to be used—and they are often the simplest and most politically expedient regulatory tool—they are most easily justified by reference to a broad consensus. Without consensus that the prohibited conduct is generally offensive to some identifiable social norm the enactment of criminal offences may be seen to lack legitimacy.

Whatever regulatory scheme is adopted it should reflect the reality that, for many reproductive genetics practices, there is no social consensus regarding the potential harms and benefits. This is in part due to a problem of incommensurability. For some, the “harms” and “potential benefits” cannot be compared in strict utilitarian fashion, especially when apparent moral harms, or harms to dignity are compared with potential therapeutic benefits.<sup>19</sup>

It would be wrong to frame this only as a problem of the lay public. There is little consensus in the academic community regarding the nature and severity of these social concerns. Nor is there agreement among elected officials, organised religion, or patient advocacy groups. Finally, there is little empirical evidence to suggest which method of regulating reproductive genetics will best accommodate the public’s concerns about these technologies.

This is not to suggest that we discount the role of the public. Indeed, finding appropriate policy must involve and promote serious moral debate. By serious moral debate we mean the willingness of those who have different (and sometimes profoundly different) beliefs to hear alternative points of view, and be open to the possibility of seeking compromising policy solutions. The goal is not, however, to achieve unanimity but to inform the establishment of responsible public policy that is respectful of the diverse nature of public concern and opinion.

### Health and safety arguments

A second way to justify a ban on many reproductive genetic practices is to base them on particular health and safety concerns. Few disagree with the conclusion of the National

Bioethics Advisory Commission that reproductive cloning is unsafe, a conclusion used to support a continued moratorium on the use of federal funds to conduct embryo research.<sup>20</sup> Relying on health and safety concerns alone as the basis for a prohibition is problematic, however, for three reasons. First, while a number of new reproductive genetic practices are clearly unsafe, (the most obvious of which is human reproductive cloning which presents risks to the developing fetus, the mother, and potentially to the born offspring) many controversial practices, such as sex selection and therapeutic cloning, are not associated with easily defined or specific health risks.

Second, since many of the identified health and safety concerns are a function of the state of contemporary scientific knowledge, it is possible that some of the concerns will be resolved in the future. If restrictions on various applications of reproductive genetics are based on outdated scientific concerns their relevance will undoubtedly fade as the science moves forward and social attitudes shift. This presents something of a “catch 22”: if the technologies are believed to be unsafe and are prohibited on this basis, then the research that may, one day, resolve the safety issues cannot proceed. If the prohibitions are in reality a reflection of both safety and deeper ethical concerns these must both be part of the background policy conversation.

### Intuitive and foundational ethical arguments

Many of the ethical concerns that are voiced with respect to reproductive genetics remain difficult to translate into policy solutions. These concerns include—for example, worries about how germline interventions will infringe human dignity and about how increasing knowledge of the functions of genes will affect existing definitions of health, disease, and disability, and considerations of the moral status of the embryo. Because these deep ethical concerns are not amenable to scientific resolution and because there is still disagreement about how they are implicated in reproductive genetics, it is difficult for policy makers to rely on them as the *sole* basis for the development of rigid prohibitions. That is, absent other rationales—such as health and safety or a clear public mandate—current ethics based arguments also seem to be an insufficient policy justification for the use of prohibitions. What is needed is further work to examine what these concerns mean in specific contexts and how more nuanced regulation might create limits for technology that respect these concerns yet provide a means for finding a careful way forward.

It would be preferable to have a clear, unambiguous ethical framework to guide the development of policy. Because, however, this is clearly absent, policy makers often fall back on a claim of general social anxiety as a rationale for legislative action. Although it is important to respect these views, legislated prohibitions must be based on more than “intuitive ethics”, famously described by Leon Kass as “the wisdom of repugnance” or the “yuck” factor.<sup>21–23</sup>

Though moral unease may be a justification for caution and should be motivation for further analysis, it is an insufficient reason for the introduction of rigid prohibitions—particularly in an area where social mores have been seen to shift rapidly. For one thing, moral unease is difficult to explain in terms that facilitate a transparent regulatory strategy. This is a challenge for policy makers; in a technology driven economy, given enough time, despite opposition to technologies widely regarded as immoral or otherwise inappropriate, social concern may eventually give way to social accommodation. This is not to say that we should not respect our sense of moral unease. We do need, however, to question whether that unease is founded on legitimate and/or enduring values that remain foundational irrespective of

scientific advance—for example, a respect for the equality of all humans—or whether the unease can be mitigated by time, wide ranging public debate, further scientific knowledge, experience with the technology, and public confidence in society's capacity to minimise harm and maximise benefit through a responsive regulatory framework.

### The rapid pace of scientific and technological developments

One of the most obvious problems with legal prohibitions is that they do not have the flexibility essential to regulate an area as rapidly evolving and scientifically complex as reproductive genetics.<sup>24–26</sup> This problem is well demonstrated by the recent debates in the UK regarding the definition of “embryo”. The 1990 Human Fertilisation and Embryology Act was thought to cover all embryo research, storage, and creation. In fact, the question has arisen whether the act can be said to apply to embryos created by cloning, rather than by fertilisation.<sup>27</sup> In other situations, the rapid advances in science, such as in the area of human embryonic stem cell research, has caused countries to revisit existing rigid prohibitions.<sup>28</sup>

In the end, the obsolescence of some legislated bans seems inevitable. Consequently, what is needed is not a technology by technology list of prohibitions. Such an approach will only create a chaotic, inconsistent patchwork of laws with little relation to each other. Rather, what is required is a flexible, scientifically informed, and responsive oversight scheme.

### MOVING TOWARDS A SOLUTION

In our view, legislated bans and prohibitions often amount to little more than ad hoc and short term solutions to often complex social and ethical issues. We expect that science will continue to move forward, that social attitudes will continue to evolve, and that policy makers will continue to struggle with crafting the right balance between encouraging scientific progress and limiting this progress in the face of uncertainty, risk, and social opinions. In such an environment, what can be done?

We recommend the adoption of a flexible and adaptive regulatory model, not unlike that which currently exists in the United Kingdom to regulate the conduct of research on reproductive genetics: a model that uses licensing methods to ensure strict compliance with a set of publicly accessible guidelines. Others have proposed similar approaches, including:

- The Hastings Center<sup>29–30</sup>;
- The National Research Council<sup>31</sup>;
- The Canadian Bar Association<sup>32</sup>; and
- The California Advisory Committee on Cloning.<sup>33</sup>

### Characteristics of the proposed model

Though extensive details of such a scheme are beyond the scope of this paper, we believe that any future scheme should strive to incorporate the following characteristics.

First, those responsible for creating a regulatory scheme must be knowledgeable and informed in the scientific, technological, and ethical issues. Second, recommendations for governance should be broadly and generally framed to allow the regulatory scheme to adapt to changes in science and social mores. That is, the enabling legislation should set the framework, articulate the relevant values and guiding principles, and set the standards for analysis; but the details of regulation, including the handling of the relevant definitions, should be left to a regulatory body.<sup>26–34</sup> Third, the regulatory body should facilitate and encourage an ongoing public and interdisciplinary discussion.<sup>35–36</sup> Fourth,

any regulatory body created should have oversight powers with respect to reproductive genetics in both the public and private sectors. It makes little sense to carefully regulate only publicly funded research while leaving all the other activities to the whims of the marketplace.

Finally, the enabling legislation should be framed to permit regulators to develop familiarity with the science and technology so that they can develop an expertise in reproductive genetics. Such expertise will permit foresight and a deep understanding of not only the science but also the social implications that a particular application of reproductive genetics brings to bear. It will be important—for example, for those involved in regulating reproductive genetics to identify when protocols or techniques involve modification of the human germline, or where issues of human dignity may be implicated.

### Barriers to implementation

There are, of course, problems with this flexible, regulatory, approach. It can certainly be argued that unambiguous prohibitions may have more symbolic weight than the scheme we propose. We question, however, whether strong symbolic censure should be a key feature of a scheme built on an unclear and shifting public and ethical mandate. In addition, as we have noted about the approach taken in the United Kingdom, regulatory bodies need not be low profile bureaucratic entities. On the contrary, the regulatory scheme should be structured to be an ongoing focal point of public discussion and, as such, will represent a commitment to open and thoughtful dialogue.

In addition, politicians may feel uncomfortable abdicating their power to a regulatory body. This accounts for some of the reluctance to establish permanent advisory committees to address bioethics issues, particularly in the United States.<sup>37</sup> In other words, is it appropriate to remove the issues associated with reproductive genetics from the oversight of democratically elected officials?

This is a legitimate concern. Appropriate checks and balances can, however, be put in place to ensure transparency of the regulatory process as well as continued oversight and accountability by elected officials. The Canadian Bar Association—for example, recommends the use of “negative resolution.”<sup>32</sup> With such a scheme, the regulations proposed by the body would come into effect and would remain in effect unless rejected by a negative vote of the House of Commons. This approach retains the needed flexibility and informed decision making but allows elected representatives to become involved in truly controversial decisions.

Perhaps most significant, however, is the fact that there are often legal and political barriers that would frustrate the implementation of a regulatory approach. In many jurisdictions—for example, in Canada and the United States—policy makers may not have many regulatory options at their disposal. In Canada—for example, there are questions regarding whether the federal or provincial government has jurisdiction over the regulation of reproductive genetics.<sup>16</sup> In the United States, abortion politics has played a dominant role in many national debates in health care. In addition, given the divided nature of public opinion, there may be little political will to create a regulatory body that will have the power to make definitive decisions about controversial topics. Given the significance of the issues at play, these structural and political obstacles should not be allowed to dominate policy development.

### CONCLUSION

The challenges associated with the regulation of reproductive genetics will endure. No law or policy will or should aim to bring closure. We need to develop a regulatory regime that



can work within this reality. Steps must be taken now to move towards a flexible regulatory scheme that promotes ongoing public and professional dialogue, sets limits which respect the ethical commitments we hold as a society, and fosters a climate which will promote valid scientific and clinical endeavour. Prohibitory bans seem to be the least appropriate tool in this context.

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